Washington State Health Care Authority

Change Summary

Manufacturers Data Submission Guide v1.2 and v1.3

The changes between version 1.2 and 1.3 of the manufacturer data submission guides (DSG) are indicated in red in the table below.

Type of change	Template	Version 1.2. (former)	Version 1.3 (current)
Language p. 2			Technical Support For any technical data related questions, or any questions regarding the data submission process, please contact the technical support staff by sending an email to: HCADPTTechSupport@hca.wa.gov
Language p. 2		HCA has filed a CR101 to revise WAC 182-51-0600, to give manufacturers additional time to report information required on new covered drugs under RCW 43.71C.050. Until the rule is revised, HCA will not initiate enforcement under RCW 43.71C.090 for manufacturers who do not report the information required by RCW 43.71C.050 prior to release of a new covered drug to the market.	HCA has filed a CR101 to revise WAC 182-51-0600, to give manufacturers additional time to report information required on new covered drugs under RCW 43.71C.050 and to clarify the reporting requirements that are due December 31, 2020. Until the rule is revised, HCA will not initiate enforcement under RCW 43.71C.090 for manufacturers who do not report the information required by RCW 43.71C.050 prior to release of a new covered drug to the market or the information required by WAC 182-51-0600(1).
Language p. 6		If your submission passes the automated validation, you will receive an email confirming this at the registered email address for your organization. If you do not receive an automated notification of either success or failure within 72 hours, please contact DPT program staff at drugtransparency@hca.wa.gov for confirmation that your submission was received, and processed	If your submission passes the automated validation, you will receive an email confirming this at the registered email address for your organization. If you do not receive an automated notification of either success or failure within 72 hours, please contact DPT program staff at HCADPTTechSupport@hca.wa.gov for confirmation that your submission was received, and processed
Description: Chemical/Biochemical/Blood Product Name	Manufacturer Covered Drugs Manufacturer New Drugs	Ingredient name including the salt form if any, without any other modifying elements, to be used as a grouper. For example, "fluoxetine" and "fluoxetine HCL" is acceptable. "Fluoxetine DR," "fluoxetine 20 mg tablets" are unacceptable for this field.	Ingredient name including the salt form if any, without any other modifying elements, to be used as a grouper. For example, "fluoxetine" and "fluoxetine HCL" is acceptable. "Fluoxetine DR," "fluoxetine 20 mg tablets" are unacceptable for this field.

			If the chemical/biochemical/blood product name is greater than 80 characters insert the chemical/biochemical/blood product name as it appears in First Databank or Medispan.
Description: Ingredient Name	Manufacturer Covered Drugs Manufacturer New Drugs	Ingredient name, may include salt form, dosage form, strength, and any other information. For example, "fluoxetine 20 mg tablets" is acceptable. "fluoxetine", "fluoxetine HCL", "fluoxetine DR, are unacceptable for this field.	Ingredient name, may include salt form, dosage form, strength, and any other information. For example, "fluoxetine 20 mg tablets" is acceptable. "fluoxetine", "fluoxetine HCL", "fluoxetine DR, are unacceptable for this field. If the ingredient name is greater than 80 characters insert the ingredient name as it appears in First Databank or Medispan.
Description: Label Name	Manufacturer Covered Drugs	Proprietary or legal name as marketed by manufacturer. For example, "fluoxetine HCL", "fluoxetine DR, are acceptable. This field should not include strength or dosage form. If unknown insert the name used to identify the drug in the clinical trials.	Proprietary or legal name as marketed by manufacturer. For example, "fluoxetine HCL", "fluoxetine DR, are acceptable. This field should not include strength or dosage form. If unknown insert the name used to identify the drug in the clinical trials. If the label name is greater than 80 characters insert the label name as it appears in First Databank or Medispan.
Description and Specification: Label Name	Manufacturer New Drugs	Name: Label Type: String Max Length: 80 characters Format: ABCDE Proprietary or legal name as marketed by manufacturer. For example, “Prozac”, "fluoxetine HCL", "fluoxetine DR, are acceptable.	Name: Label/Pipeline Name Type: String Max Length: 80 characters Format: ABCDE Nullable Proprietary or legal name as marketed by manufacturer. For example, “Prozac”, "fluoxetine HCL", "fluoxetine DR, are acceptable. If the label name has not been determined then use the pipeline name or drug identifier (e.g. ABC1234). If the label name is greater than 80 characters insert the label name as it appears in First Databank or Medispan.
Specification: Application Number	Manufacturer New Drugs	Name: Application Number Type: Numeric Format: 000000 Max Length: 6 digits Min Length: 6 digits	Name: Application Number Type: Numeric Format: 000000 Max Length: 6 digits Min Length: 6 digits Nullable
Specification: Application Supplement Number	Manufacturer New Drugs	Name: Application Supplement Number	Name: Application Supplement Number

		Type: Numeric Format: 0000 Max Length: 4 digits Min Length: 4 digits	Type: Numeric Format: 0000 Max Length: 4 digits Min Length: 4 digits Nullable
Specification: Significant Impact on State Expenditures	Manufacturer New Drugs	Name: Significant Impact on State Expenditures Type: Choice Choices: Y,N	Name: Significant Impact on State Expenditures Type: Choice Choices: Y,N Nullable